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(54) Asymmetric water jet atherectomy.

(57) A technique for ablation and removal of plaque (120) deposits from the arterial, venous, vascular graft or other tissue wall (110) of a patient. Ablation is accomplished by directing a high pressure jet (129) of sterile saline solution at the plaque deposit. The high pressure jet is located at the distal end of a catheter (12) which is advanced through the vascular system to the site of the plaque deposit. Removal of the debris is via an evacuation lumen (128) within the catheter.

The arterial wall is protected from damage by the catheter design which directs the high pressure jet towards a portion of the distal end of the catheter which serves as a target. The distal end of the catheter is placed such that the plaque or other deposit to be ablated is positioned between the high pressure jet and the target.

An optional ultrasonic transducer array (118) located adjacent the high pressure jet and the evacuation lumen permits the attending physician to monitor the procedure.

A balloon (113) may be used to hold the catheter against the deposit allowing it to protrude into the ablation jet and be removed from the vessel.

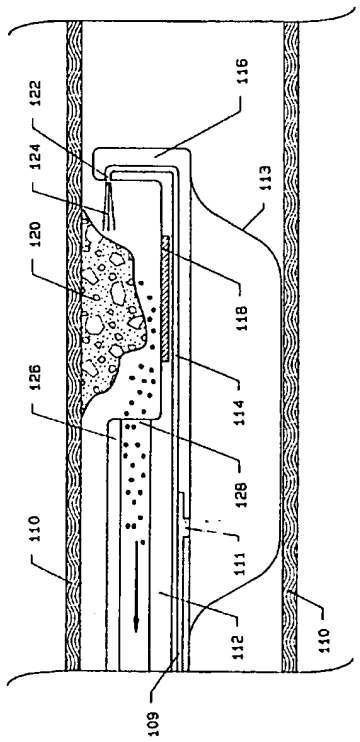

FIG. 3A

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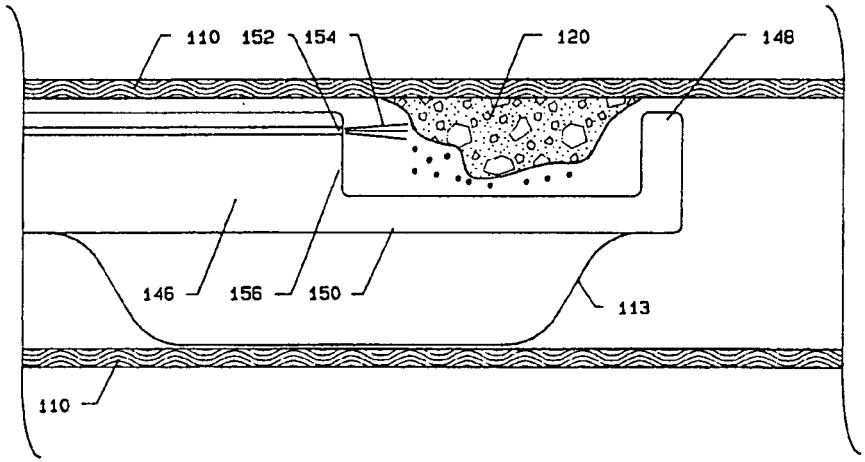
110
152
154
120
148
146
156
150
113
110

FIG. 3C

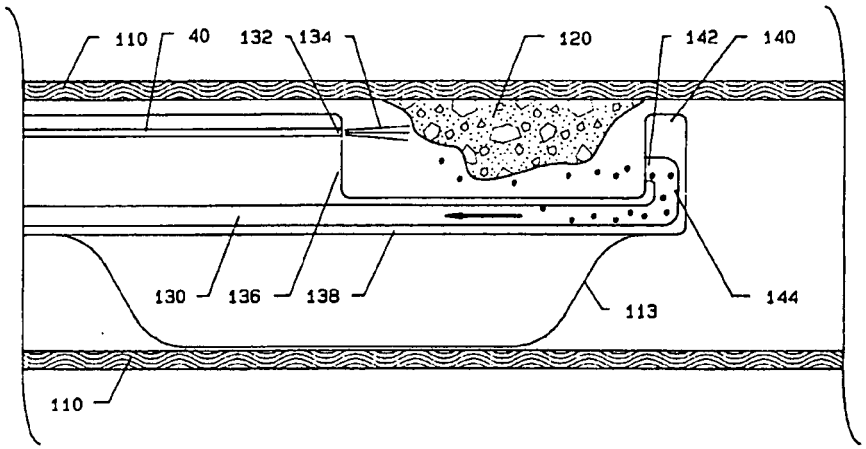
110
40
132
134
120
142
140
130
136
138
113
144
110

FIG. 3B

The present invention relates to apparatus and method for ablating an undesirable material within the body of a patient.

Methods and apparatus have previously been proposed for removing tissue and various deposits from the body of a patient. US Patent No. 4 790 813 issued to Kensey and US. Patent No. 4 842 579 issued to Shiber describe techniques for the removal of plaque deposited in arteries by mechanical ablation using rotating cutting surfaces. These relatively traumatic approaches are directed to the treatment and removal of very hard substances.

Pressurized fluids have been proposed to flush undesirable substances from body cavities. U.S. Patent No. 1 902 418 describes such a system for flushing body cavities of domesticated animals. More modern proposals tend to use vacuum rather than gravity as the primary means for removal of the deposits or tissue and to use relatively low fluid pressures for ablation. Thus, U.S. Patent No. 3 930 505 issued to Wallach describes a surgical apparatus for the removal of tissue from the eye of a patient. As with similar systems, Wallach uses a relatively low pressure jet of water (i.e. 15 to 3500 psi) to disintegrate the tissue, and a suction pump to perform the actual removal.

A similar approach applied to the cardiovascular system is discussed in US Patent No. 4 690 672 issued to Veltrup. Veltrup also provides a low pressure jet of water (i.e. less than 450 psi) to ablate the deposits. As with Wallach, Veltrup uses a vacuum pump for evacuation of the fragments. It seems apparent that the prior art uses only relatively low pressure jets for safety reasons.

The present invention, on the other hand, provides apparatus and method for ablating deposits from vessels, that is, cavities of humans or animals, using fluid under high pressure yet avoiding trauma to the body of the patient.

Accordingly, in a first aspect the present invention provides an apparatus for ablating a deposit within a vessel of a patient, characterised in that it comprises:

a. a catheter (12) having a proximal end and a distal end (56);

b supplying means (38) coupled to said proximal end of the catheter for supplying a fluid under high pressure;

c. directing means (122.132) coupled to said distal end of the catheter for directing a stream of the fluid under high pressure at the deposit; and

d. preventing means (126, 140) coupled to said distal end of the catheter for preventing the stream of fluid under high pressure from directly impinging upon the vessel.

In a second aspect the invention provides a method for ablating a deposit in a vessel of a patient, characterised in that it comprises:

advancing a catheter with a proximal end and a distal end until said distal end of the catheter is positioned at the site of the deposit;

supplying a stream of high pressure fluid to impinge upon the deposit thereby to ablate it; and

interposing a target intermediate the stream of high pressure fluid and the vessel to protect the vessel from the stream of high pressure fluid.

If desired, the catheter used in the apparatus or method of the present invention can be one disclosed in our copending European Application 91 307 140.3, filed 2 August 1991.

The term "high pressure" as used herein with reference to the ablating liquid or other fluid refers to pressures above 3,500 pounds per square inch (p.s.i.), for example, pressures in the range 5,000 to 50,000 p.s.i., especially 25,000, 30,000, 35,000 or other value in the range 20,000 to 40,000.

In preferred forms the present invention overcomes the disadvantages of the prior art by providing a catheter for the ablation and removal of hardened or other deposits from a vessel of a patient. The term "vessel" as used herein refers, for example, to the cardiovascular system, vascular grafts, ureters, fallopian tubes, and other tubular tissues or cavities within the body. The high pressure jet is located at the distal end of a catheter which is advanced through the arterial system to the location of the deposit. The stream of high pressure saline solution ablates the deposit upon contact. The resulting fragments are usually removed through an evacuation lumen, and the force of the jet on the evacuation lumen can serve as a pump to remove the fragments through the catheter as positive pressure; evacuation does not require a vacuum.

The procedure is rendered inherently safe by directing the high pressure jet toward a target or shield also located at or adjacent the distal end of the catheter. In this way the vessel wall is protected from inadvertent damage from a misdirected high pressure stream of saline solution.

In operation, the deposit to be ablated and removed is between the high pressure jet and the target. A number of configurations are useful. For example, the jet may be located proximal of the target and be directed distally. Alternatively, the jet may be directed proximally and be located distal of the target. With either configuration, the jet may be directed parallel to the longitudinal axis of the artery. In the alternative, the jet may have a component which projects radially outward or radially inward; in this alternative, the target, if desired, can be located closer or farther from the central axis than the high pressure jet.

Other options include multiple high pressure jets. To improve monitoring possibilities during the procedure, an ultrasonic transducer array may be appropriately positioned at the distal end of the catheter. The transducer array may be directed toward the deposit or toward a mirror directed toward the deposit. An angioscope or other diagnostic device may also be

used with the catheter to identify the presence of plaque or thrombus. The catheter may provide a separate lumen for passage of such devices, or the lumen may also be used for evacuation of particulate material.

A distal balloon may be used to hold the catheter to one side of the vessel for removal of the deposit from that wall. This deposit ablation and removal forms the atherectomy function of the catheter. An additional balloon may also be placed on the catheter to provide dilatation of the vessel following deposit removal. This second balloon provides an angioplasty function for the catheter.

An additional passage can be provided for flushing the vessel, infusion of drugs, and/or injecting contrast medium for visualization. The evacuation lumen can be used for these functions.

There are now described, by way of example and with reference to the accompanying drawings, preferred embodiments of the apparatus and method aspects of the present invention.

In the drawings:

FIG. 1A is a plan view of an atherectomy system employing the present invention;

FIG. 1B is a plan view of an atherectomy system having ultrasonic monitoring;

FIG. 2A is a close-up sectioned view of manifold 14;

FIG. 2B is a functional view of manifold having ultrasonic monitoring;

FIG. 3A is a conceptual view of the operation of an atherectomy device or apparatus having a distal jet and proximal target;

FIG. 3B is a conceptual view of the operation of an atherectomy device having a proximal jet and distal target;

FIG. 3C is a conceptual view of the operation of an atherectomy device having no evacuation lumen;

FIG. 4 is a longitudinal sectioned view of the distal end of a catheter employing a first embodiment of the present invention;

FIG. 5 is a transverse sectioned view of the catheter of Fig. 4;

FIG. 6 is a transverse sectioned view of the catheter of Fig. 4;

FIG. 7 is a transverse sectioned view of the catheter of Fig. 4;

FIG. 8 is a longitudinal sectioned view of the distal end of a catheter employing a second embodiment of the present invention;

FIG. 9 is a transverse sectioned view of the catheter of Fig. 8;

FIG. 10 is a longitudinal sectioned view of the distal end of a catheter employing a third embodiment of the present invention;

FIG. 11 is a transverse sectioned view of the catheter of Fig. 10;

FIG. 12 is a transverse sectioned view of the catheter of Fig. 10;

FIG. 13 is a transverse sectioned view of the catheter of Fig. 10;

FIG. 14 is a longitudinal sectioned view of the distal end of a catheter employing a fourth embodiment of the present invention;

FIG. 15 is a transverse sectioned view of the catheter of Fig. 14;

FIG. 16 is a transverse sectioned view of the catheter of Fig. 14;

FIG. 17 is a longitudinal sectioned view of the distal end of a catheter employing a fifth embodiment of the present invention;

FIG. 18 is a transverse sectioned view of the catheter of Fig. 17;

FIG. 19 is a transverse sectioned view of the catheter of Fig. 17;

FIG. 20 is a transverse sectioned view of the catheter of Fig. 17;

FIG. 21 is a longitudinal sectioned view of the distal end of a catheter employing a sixth embodiment of the present invention;

FIG. 22 is a transverse sectioned view of the catheter of Fig. 21;

FIG. 23 is a transverse sectioned view of the catheter of Fig. 21;

FIG. 24 is a transverse sectioned view of the catheter of Fig. 21;

FIG. 25 is a longitudinal sectioned view of the distal end of a catheter employing a seventh embodiment of the present invention;

FIG. 26 is a transverse sectioned view of the catheter of Fig. 25;

FIG. 27 is a transverse sectioned view of the catheter of Fig. 25;

FIG. 28 is a longitudinal sectioned view of the distal end of a catheter employing an eighth embodiment of the present invention;

FIG. 29 is a transverse sectioned view of the catheter of Fig. 28;

FIG. 30 is a transverse sectioned view of the catheter of Fig. 28;

FIG. 31 is a longitudinal sectioned view of the distal end of a catheter employing a ninth embodiment of the present invention;

FIG. 32 is a transverse sectioned view of the catheter of Fig. 31;

FIG. 33 is a transverse sectioned view of the catheter of Fig. 31;

FIG. 34 is a transverse sectioned view of the catheter of Fig. 31;

FIG. 35 is a longitudinal sectioned view of the distal end of a catheter employing a tenth embodiment of the present invention;

FIG. 36 is a transverse sectioned view of the catheter of Fig. 35;

FIG. 37 is a transverse sectioned view of the

catheter of Fig. 35;

FIG. 38 is a transverse sectioned view of the catheter of Fig. 35;

FIG. 39 is a longitudinal sectioned view of the distal end of a catheter employing an eleventh embodiment of the present invention;

FIG. 40 is a transverse sectioned view of the catheter of Fig. 39;

FIG. 41 is a transverse sectioned view of the catheter of Fig. 39;

FIG. 42 is a transverse sectioned view of the catheter of Fig. 39;

FIG. 43 is a longitudinal sectioned view of the distal end of a catheter employing a twelfth embodiment of the present invention;

FIG. 44 is a longitudinal sectioned view of the distal end of a catheter employing a thirteenth embodiment of the present invention;

FIG. 45 is a transverse sectioned view of the catheter of FIG. 44; and,

FIG. 46 is an end view of the catheter of FIG. 44.

FIG. 1A is a plan view of an atherectomy catheter system 10 employing the present invention. Catheter 12 is introduced into an artery of the patient at a convenient location, usually the femoral artery. Distal end 56 is advanced to the site of the deposit to be ablated. Ordinarily, this site will have been previously identified using a suitable diagnostic procedure such as angiography. After location at the site of the deposit, the apparatus at distal end 56 of catheter 12 serves to ablate and remove the deposit as explained in more detail below.

Manifold 13 sealingly couples to the proximal end of catheter 12 and serves to provide separate access to the various lumens of catheter 12. Main branch 36 of manifold 13 sealingly couples to guide wire 32 to assist in positioning catheter 12 in the manner known in the art. Positioning knob 34 assists the medical attendant in this procedure.

Secondary branch 38 of manifold 13 permits access to catheter 12 to supply the sterile saline solution under high pressure. Hypo tubing 40 is drawn from stainless steel to have the strength to handle the pressures up to 50,000 psi and yet remain flexible enough to be positioned transarterially. Typical pressure is 30,000 psi within the range of 5,000 to 50,000 psi. Hypo tubing 40 traverses the entire length of catheter 12 from distal end 56 to secondary branch 38. Preferably and not by way of limitation, sterile saline is supplied by disposable saline solution bag 48. Low pressure tubing 50 conveys the sterile saline solution to high pressure piston pump 42. After pressurization by high pressure piston pump 42 of typically about 30,000 psi, the sterile saline solution is transported in the direction of arrow 44 through hypo tubing 40 to distal end 56 of catheter 12. Safety monitor 52 functions to shut off high pressure piston pump 42 if a failure occurs.

Secondary branch 22 of manifold 13 is coupled to the evacuation lumen of catheter 12. Fragments of the ablated deposit are channeled from secondary branch 22 through low pressure tubing 26 in the direction of arrow 46. Safety monitor 24 ensures that the volume of effluent and pressures within the system are maintained within allowable tolerances. Peristaltic pump 28 meters the rate at which effluent is evacuated to disposable bag 30. The environment in which the ablation procedure occurs is greater than one atmosphere due to the impingement of the jet on the evacuation lumens. Peristaltic pump 28 meters evacuation of the effluent without ever creating a vacuum.

FIG. 1B is a plan view of an alternative embodiment of the present invention. This catheter system includes all of the features of catheter system 10 with an inflatable distal balloon and ultrasonic monitoring.

Distal balloon 58 may be inelastic, such as those used in balloon dilatation. The balloon serves to hold the catheter close to one side of the vessel and force the plaque, thrombus, or atheromatous material to protrude into the pathway of the saline jet(s). An additional balloon (not shown) may be located on the distal end of the catheter to serve as a vessel dilatation balloon to be used after removal of the deposited material.

In the alternative embodiment, manifold 13 (see also Fig. 1A) is replaced with manifold 14 having additional secondary branch 20. The inflation lumen of catheter 12, which is coupled to distal balloon 58, is sealingly coupled through secondary branch 20 and flexible tubing 54 to balloon inflation device 16. In this way, distal movement of thumb plunger 18 causes inflation of distal balloon 58.

An additional feature of the alternative embodiment is ultrasonic monitor 60 which is coupled via cable 64 to an ultrasonic transducer array (not shown in this view) located at distal end 56. Medical personnel may view the ablation procedure on screen 62 of ultrasonic monitor 60.

FIG. 2A is a longitudinal sectioned view of manifold 14. It is preferably molded from a rigid plastic as two halves which are bonded together and are adhesively coupled at points 70, 76, 80, 84, 98, and 100. Catheter 12 is sealingly coupled to the distal end of manifold 14 using known techniques.

Lumen 82 of secondary branch 22 is sealingly coupled to evacuation lumen 74. In most embodiments, evacuation lumen 74 will be the largest lumen of catheter 12. Evacuation lumen 74 may also be coupled to main branch 36. Compression nut 88 attaches via threads 86 to compress o-ring 90 to sealingly engage guide wire 32. During initial positioning of catheter 12, guide wire 32 may be located within evacuation lumen 74.

Lumen 72 contains hypo tubing 40 which enters secondary branch 38, bends obliquely at point 94 and

extends the length of lumen 72 distal to point 94.

Also sharing lumen 72 is the function of inflating distal balloon 58. To accomplish this, lumen 66 of secondary branch 20 is coupled to lumen 72 at point 68. Fluid used to inflate balloon 58 (see also Fig. 1B) is forced through lumen 72 in that space not occupied by hypo tubing 40.

FIG. 2B is a conceptualized view of the operation of manifold 14 wherein all referenced elements are as previously described. In this view it can be seen that septum 108 serves to separate evacuation lumen 74 from lumen 72. Flexible seal 106 seals secondary branch 38 against the walls of hypo tubing 40.

FIG. 3A is a conceptual view of the operation of the distal end of an atherectomy catheter shown partially cutaway. In the embodiment shown, single high pressure jet 122 is positioned at the distal end of the catheter and is directed in a proximal direction. Evacuation lumen 128 of the catheter provides the target for high pressure jet 122 ensuring that high pressure saline stream 124 cannot directly contact the walls of artery 110.

Distal end of hypo tubing 114 is bent as shown to supply high pressure jet 122. Main catheter body 112 is narrowed at 114 to provide access to deposit 120. Balloon inflation lumen 109 is connected to balloon inflation port 111 to provide access for inflation of balloon 113. The balloon holds the catheter against the deposit on the opposite wall for ablation and removal.

To ablate deposit 120, the catheter must be positioned such that deposit 120 is located between wall 126 and high pressure jet 122 as shown. As deposit 120 is ablated by high pressure saline stream 124, particles are evacuated by evacuation lumen 128 as shown. These particles are propelled proximally by the stagnation pressure formed at the distal port of evacuation lumen 128 from the action of high pressure saline stream 124.

An optional ultrasonic transducer array 118 may be used to monitor the ablation and removal operation (see also Fig. 1B). This feature is addressed in more detail below.

FIG. 3B is a conceptual view of the operation of an alternative embodiment of an atherectomy catheter. This embodiment features wall 136 having single high pressure jet 132 which generates a high pressure saline stream 134 directed distally. Distal end 140 of the catheter operates as the target to protect the walls of artery 110 from damage by impingement of high pressure saline stream 134.

This configuration permits the distal end of hypo tubing 40 to remain straight and without any bends. However, evacuation lumen 130 must be sufficiently small to fit within narrowed portion 138 of the catheter and must bend at a ninety degree angle to position evacuation port 142 for receipt of the particles to be removed. This embodiment may have an optional ultrasonic monitor array, although none is shown. Balloon 113 is inflated and used as previously discussed.

FIG. 3C is a conceptual view of the operation of another embodiment of an atherectomy catheter. This embodiment is similar to the embodiment of Fig. 3B, except that it has no evacuation lumen. With this approach, deposit 120 is ablated into particles which are sufficiently small as not to cause down stream vessel occlusion prior to removal from the body under normal biochemical processes.

Because no evacuation lumen is present, main catheter body 146 may have a lesser diameter. Wall 156 having high pressure jet 152 yielding high pressure saline stream 154 may be correspondingly smaller. Similarly, narrow portion 150 and target wall 148 may be correspondingly smaller permitting the atherectomy device to be used in smaller vessels. Balloon 113 is inflated and used as previously discussed.

FIG. 4 is a longitudinal sectioned view of distal tip 158 of an atherectomy catheter according to the present invention. In this embodiment, a separate guide wire lumen 166 is open at the distal tip 168. This provides for ease in positioning of the atherectomy device as an "over the wire" catheter.

Blunt tip 164 is molded in the shape shown with upper appendage 162 providing the target to protect the arterial wall from direct impingement of a high pressure saline stream.

Hypo tubing 174 is coupled to nozzle assembly 161 having jet orifice 160 of approximately .001 inch. In accordance with the present invention, the saline stream emitted from jet orifice 160 will have a pressure of approximately 30,000 psi. The high pressure saline stream from jet orifice 160 is directed distally within the projected span of upper appendage 162 for the safety reasons discussed above. Ablated particulate matter enters evacuation lumen 172 via evacuation port 170. In this embodiment, no ultrasonic transducer array is present.

This particular embodiment of the present invention is configured to operate most efficiently to ablate relatively small, but highly calcified deposits attached to the wall of an artery. It is not well suited to situations involving total occlusions or occlusions which are so complete as to preclude positioning blunt tip 164 and upper appendage 162 distal of the deposit. A distal balloon is not shown in this embodiment although one can be placed in a manner similar to those which follow.

FIG. 5 is a transverse sectional view of the atherectomy device of Fig. 4. Catheter body 159 has an evacuation lumen 172, a guide wire lumen 166, and nozzle assembly 161.

FIG. 6 is a transverse sectional view of the atherectomy device of Fig. 4 as taken proximal to Fig. 5. All reference components are as previously described.

FIG. 7 is a transverse sectional view of the

atherectomy device of Fig. 4 as taken proximal to Fig. 6. Note that for most of its length, catheter body 159 has evacuation lumen 172 as constituting the majority of the cross sectional area. This provides the greatest assurance that evacuation lumen 172 will not clog with particulate matter.

FIG. 8 is a longitudinal sectioned view of the distal end 176 of an atherectomy device which is useful for ablating deposits in arteries which have a greater percentage of occlusion. In this configuration, nozzle assembly 161 has a high pressure jet 163 which is angled toward the central longitudinal axis of the catheter. In this way, the effective diameter of the catheter distal to high pressure jet 163 is substantially less than the diameter proximal to that point. The result is that the high pressure saline stream tends to cut away at the proximal surface of the deposit rather than longitudinally as with the embodiment of Fig. 4.

As with the other embodiments, high pressure jet 163 is directed toward distal end 176 as a safety measure. The distal tip is truncated along slope 182 to provide space for positioning the deposit. Distal end 180, though much smaller in this embodiment, must yet be rounded to prevent trauma. A distal balloon is not shown in this embodiment. One can be added to hold the catheter preferentially against one side of the vessel. The device can also function without a balloon to follow a wire across a lesion and enlarge the opening.

FIG. 9 is a transverse sectioned view of the atherectomy device of Fig. 8. Evacuation port 178 is entered at an angle by the particulate matter to be removed (see also Fig. 8). All other referenced elements are as previously described.

FIG. 10 is a longitudinal sectioned view of the distal end 184 of an atherectomy device without guide wire lumen. Positioning of this device at the site of the deposit must be performed without the aid of a guide wire. Often times a guide catheter is used with such devices.

Catheter body 200 is extruded in the standard fashion. Distal tip 186 is then affixed at 198 with adhesive, heat sealing, or other suitable attachment technique. Evacuation port 188 and tip evacuation lumen 194 are molded into distal tip 186 in the positions shown. Hypo tubing 192 is attached to nozzle assembly 191 containing high pressure jet 190 as previously described.

This particular embodiment performs much in the same fashion as the embodiment of Fig. 4. The major difference is that this embodiment does not have a guide wire lumen.

This catheter is shown without a balloon although one can be added to the side opposite the jet. The balloon holds the catheter against the deposit on one side of the vessel wall.

FIG. 11 is a transverse sectioned view of the catheter of Fig. 10. All referenced elements are as previously described.

FIG. 12 is a transverse sectioned view of the catheter of Fig. 10 taken proximal of Fig. 11. All referenced elements are as previously described.

FIG. 13 is a transverse sectioned view of the catheter of Fig. 10 taken proximal to distal tip 186. As can be seen with previous embodiments, evacuation lumen 196 occupies most of the cross sectional area of the main catheter body.

FIG. 14 is a longitudinal sectioned view of the distal end of an alternative embodiment of an atherectomy device similar to the embodiment of Fig. 8, except that it has no guide wire lumen. Distal tip 208 is molded having extension 214, evacuation port 210, tip evacuation lumen 212 and slope 206. High pressure jet 204 of nozzle assembly 202 is angled toward the central longitudinal axis as in the embodiment of Fig. 8. Again this tends to ablate the deposit from the proximal surface rather than longitudinally. A distal balloon (not shown) may be added as appropriate.

FIG. 15 is a transverse sectioned view of the atherectomy device of Fig. 14. All referenced elements are as previously described.

FIG. 16 is a transverse sectioned view of the atherectomy device of Fig. 14 taken proximal to Fig. 15. All referenced elements are as previously described.

FIG. 17 is a longitudinal view of the distal end of an atherectomy device 216 employing an alternative embodiment of the present invention. In this embodiment, hypo tubing 222 runs the length of lumen 240 of catheter body 238 to distal tip 220 where it is attached to nozzle assembly 224. In this way, hypo tubing 222 has no sharp bends near the distal end of the catheter. Lumen 240 is coupled to balloon inflation port 241 which is used to inflate balloon 243. The balloon is used to hold the catheter against the deposit on the vessel wall. The catheter may also be made without the balloon.

High pressure jet 226 of nozzle assembly 224 is angled toward the central longitudinal axis of the catheter. This permits the atherectomy device to be applied to deposits which are near to totally occluding the vessel, because the effective diameter of the device distal to the deposit comprises only the diameter of distal tip 220. End member 218 is molded to provide slope 228 and slope 232 ensuring that the high pressure saline stream from high pressure jet 226 will impinge upon the deposit to be ablated. Evacuation port 230 is open permitting the particulate matter to enter evacuation lumen 234.

As with the other embodiments wherein the high pressure jet is angled toward the central longitudinal axis, the present embodiment ablates the deposit along the proximal surface rather than longitudinally. Again, this makes the device most applicable to deposits which occupy a large fraction of the cross sectional area of the vessel lumen.

FIG. 18 is a transverse sectional view of the embodiment of Fig. 17 taken from the distal end of the atherectomy device. All referenced elements are as previously described.

FIG. 19 is a transverse sectional view of the embodiment of Fig. 17 taken proximal to Fig. 18. All referenced elements are as previously described.

FIG. 20 is a transverse sectional view of the embodiment of Fig. 17 taken proximal of end member 218. Evacuation lumen 234 occupies the majority of the cross sectional area of the main catheter body.

FIG. 21 is a longitudinal sectioned view of an atherectomy device 242 similar to the embodiment of Fig. 17, except that it has a guide wire lumen. All other referenced elements are as previously described. Balloon 243 is used to push the catheter against the deposit on the vessel wall. The catheter can also function without the balloon.

FIG. 22 is a transverse sectioned view of atherectomy device 242. It is similar to atherectomy device 216, except that it has a guide wire lumen 244. To accommodate guide wire lumen 244 with the smallest increase in distal cross sectional area, guide wire lumen 244 is located off center with respect to nozzle assembly 224.

FIG. 23 is a transverse sectioned view of atherectomy device 242 taken proximal to Fig. 22. Guide wire lumen 244 has a larger diameter than hypo tubing 2 2 2.

FIG. 24 is a transverse sectioned view of atherectomy device 242 taken proximal to end member 218. Evacuation lumen 234 is by far the largest of the three lumens. Lumen 240, which accommodates hypo tubing 222, is the smallest lumen.

FIG. 25 is a longitudinal sectioned view of an atherectomy device 246 employing another embodiment of the present invention. In this embodiment, high pressure saline transfers through hypo tubing 222 having bends at point 254 and point 256. Nozzle assembly 258 has high pressure jet 260 directed proximally. Lumen 240 of catheter body 238 couples to lumen 252, which accommodates hypo tubing 222 and is coupled to balloon inflation port 223 which is used to inflate balloon 225. Distal tip 250 of end member 248 is smoothly rounded to reduce trauma.

End member 248 is molded with surface 272 and slope 270 defining evacuation port 264. Tip evacuation lumen 266 couples to evacuation lumen 234 of catheter body 238. Surface 272 of end member 248 serves as an axial continuation of the outer surface of catheter body 238.

Atherectomy device 246 tends to supply a highly controlled high pressure saline stream at a precise delivery point. As such, it is most applicable to those applications having minimal occlusion by a very hard deposit lying very close to the vessel wall. This approach is also appropriate to complete the ablation of a deposit which is partially ablated using a different embodiment.

FIG. 26 is a transverse sectioned view of atherectomy device 246. All referenced elements are as previously described.

FIG. 27 is a transverse sectioned view of atherectomy device 246 taken proximal to Fig. 26. All referenced elements are as previously described.

FIG. 28 is a longitudinal sectioned view of an atherectomy device which is similar to atherectomy device 246, except that it has a guide wire lumen 276. All other referenced elements are as previously described. Balloon 225 is used to push the catheter against the deposit.

FIG. 29 is a transverse sectioned view of the atherectomy device of Fig. 28. All referenced elements are as previously described.

FIG. 30 is a transverse sectioned view of the atherectomy device of Fig. 28 taken proximal to Fig. 29. All referenced elements are as previously described.

FIG. 31 is a longitudinal sectioned view of atherectomy device 278. Unlike previously discussed embodiments, atherectomy device 278 has multiple high pressure jets. This makes the device best suited to ablate the hardest of deposits near the arterial wall requiring the most aggressive and most precisely controlled high pressure saline streams.

Atherectomy device 278 has an extruded catheter body 288 having an evacuation lumen 284, a guide wire lumen 282, and a lumen 290 to accommodate hypo tubing 292. Lumen 290 is coupled to balloon inflation port 291 for inflation of balloon 302. Catheter body 288 is coupled to end member 280, which is molded to have an end evacuation lumen 286 and an area for receiving the deposit to be ablated. Hypo tubing 292 has an inner lumen 294 and a bend at point 298 to produce riser 296. Nozzle assembly 300, coupled to riser 296, has a plurality of high pressure jets as is described below.

FIG. 32 is a transverse sectioned view of atherectomy device 278 taken proximal to end member 280. All referenced elements are as previously described.

FIG. 33 is a transverse sectioned view of atherectomy device 278 taken distal of Fig. 32. All referenced elements are as previously described.

FIG. 34 is a transverse sectioned view of atherectomy device 278 taken in a distal direction. Nozzle assembly 300 has a plurality of high pressure jets 301a-301n. All other referenced elements are as previously discussed.

FIG. 35 is a longitudinal sectioned view of atherectomy device 304. It is similar to atherectomy device 278, except that it has ultrasonic transducer array 310 mounted on array mounting surface 312. Each element of ultrasonic transducer array 310 is separately coupled to ultrasonic monitor 60 (see also Fig. 1B) via a different one of cables 306a-306n. All other referenced elements are as previously des-

cribed. Balloon inflation port 291 is coupled to lumen 290 for inflation of balloon 302.

FIG. 36 is a transverse sectioned view of atherectomy device 304. All referenced elements are as previously described. Note that cables 306a-306n share lumen 290 with hypo tubing 292.

FIG. 37 is a transverse sectioned view of atherectomy device 304 taken distal to Fig. 36. All referenced elements are as previously described. Ultrasonic transducer array 310 comprises separate ultrasonic transducers 308a-308n.

FIG. 38 is a transverse sectioned view of atherectomy device 304 taken in a distal direction. All referenced elements are as previously described.

FIG. 39 is a transverse sectioned view of atherectomy device 400. It is similar in construction and operation to atherectomy device 304, except that it has an integrated ultrasonic transducer assembly 428. This permits a differently constructed catheter having a relatively larger evacuation lumen 416. Ultrasonic transducer assembly 428 is internally multiplexed such that a single cable 420, coupled via connector 426, is sufficient to communicate with ultrasonic monitor 60 (see also Fig. 1B). Cable passes through a separate lumen of catheter body 418 and to connector 426 via port 422.

Balloon inflation lumen 429 is coupled to balloon inflation port 431 and is used to inflate balloon 430. Lumen 404, which extends through end member 402, provides for use with a guide wire. End evacuation lumen 414 couples evacuation port 412 to evacuation lumen 416 of catheter body 418. Nozzle assembly 410 is coupled to hypo tubing 406, which bends at point 408 as shown.

FIG. 40 is a transverse sectioned view of atherectomy device 400. All referenced elements are as previously described.

FIG. 41 is a transverse sectioned view of atherectomy device 400 taken distal of Fig. 40. All referenced elements are as previously referenced.

FIG. 42 is a transverse sectioned view of atherectomy device 400 taken in a distal direction. All referenced elements are as previously described. Nozzle assembly 410 has individual high pressure jets 432, 434, 436, 438, and 440.

FIG. 43 is a longitudinal sectioned view of an atherectomy device which is similar to atherectomy device 400, except that ultrasonic transducer assembly 442 and ultrasonic mirror 444 replace ultrasonic transducer assembly 428 of atherectomy device 400. This particular embodiment is slightly more complex to construct, but has the advantage of a larger area to accommodate the deposit to be ablated. Balloon inflation port 431 is used to inflate balloon 430.

FIG. 44 is a longitudinally sectioned view of the distal end of atherectomy catheter 446. It has an extruded outer catheter body 448 containing several lumens (see also FIG. 45). The central lumen contains sensor positioning rod 454, which is a flexible torque transmitting device used to rotate ultrasonic transducer 452 in the direction of or opposite to arrow 464. In this way, ultrasonic transducer 452 may be radially directed to monitor the desired portion of the vessel lumen.

Attached to the distal end of ultrasonic transducer 452 is distal tip 458 containing nozzle assembly 462. High pressure jet 460 of nozzle assembly 462 is directed proximally and radially outward. It produces a high pressure stream of fluid which proceeds in the direction of arrow 461. Because nozzle assembly 462 is coupled to ultrasonic transducer 452, rotation of positioning rod 454 also radially positions high pressure jet 460.

The high pressure stream of fluid is directed toward fluid evacuation port 466 to assist in evacuation of particulate matter as the deposit is ablated. With high pressure jet 460 directed along arrow 461, particulate matter is evacuated via evacuation lumen 450. Two other evacuation lumens (see also FIG. 45) provide for evacuation as nozzle assembly 462 is rotated.

FIG. 45 is a transverse sectioned view of atherectomy catheter 446. Lumens 450, 468, and 470 are all evacuation lumens. The selection of which evacuation lumen is used at any particular point in time depends upon the radial attitude of nozzle assembly 462 (see also FIG. 44). The three individual evacuation lumens are separated by septums 472, 474, and 476.

FIG. 46 is an end view of atherectomy catheter 446. All referenced elements are as previously discussed.

Claims

1. An apparatus for ablating a deposit within a vessel of a patient, characterised in that it comprises:
   a. a catheter (12) having a proximal end and a distal end (56);
   b. supplying means (38) coupled to said proximal end of the catheter for supplying a fluid under high pressure;
   c. directing means (122, 132) coupled to said distal end of the catheter for directing a stream of the fluid under high pressure at the deposit; and
   d. preventing means (126, 140) coupled to said distal end of the catheter for preventing the stream of fluid under high pressure from directly impinging upon the vessel.

2. An apparatus according to Claim 1, wherein the fluid is a saline solution.

3. An apparatus according to Claim 1 or 2, wherein

the preventing means comprises a target interposed between the directing means and the vessel.

4. An apparatus according to Claim 3, wherein the target is an integral part of the catheter.

5. An apparatus according to Claim 1, 2, 3 or 4, wherein the directing means comprises one or more high pressure jets.

6. An apparatus according to any of the preceding claims, wherein the target is distal of the directing means.

7. An apparatus according to any of Claims 1 to 5, wherein the directing means is distal of the target.

8. An apparatus according to any of the preceding claims, which includes an ultrasonic transducer array coupled to said distal end of the catheter.

9. An apparatus according to Claim 8, wherein the ultrasonic transducer array is directed toward the deposit.

10. An apparatus according to Claim 8, wherein the ultrasonic transducer array is directed toward a reflecting device.

11. An apparatus according to any of the preceding claims, wherein the directing means directs the stream of fluid under high pressure parallel to the longitudinal axis of the catheter.

12. An apparatus according to any of Claims 1 to 10, wherein the directing means directs the stream of fluid under high pressure nonparallel to the longitudinal axis of the catheter.

13. An apparatus according to any of the preceding claims, which includes evacuating means coupled to said distal end of the catheter for evacuating particulate matter ablated from the deposit.

14. An apparatus according to Claim 13, wherein said evacuating means comprises an evacuation lumen toward which the stream of fluid under high pressure is directed.

15. An apparatus according to any of the preceding claims, which includes an inflatable balloon for positioning said distal end of the catheter.

16. A method for ablating a deposit in a vessel of a patient, characterised in that it comprises:

advancing a catheter with a proximal end and a distal end until said distal end of the catheter is positioned at the site of the deposit;

supplying a stream of high pressure fluid to impinge upon the deposit thereby to ablate it; and

interposing a target intermediate the stream of high pressure fluid and the vessel to protect the vessel from the stream of high pressure fluid.

17. A method according to Claim 16, which includes monitoring the ablating with an ultrasonic transducer array coupled to said distal end of the catheter.

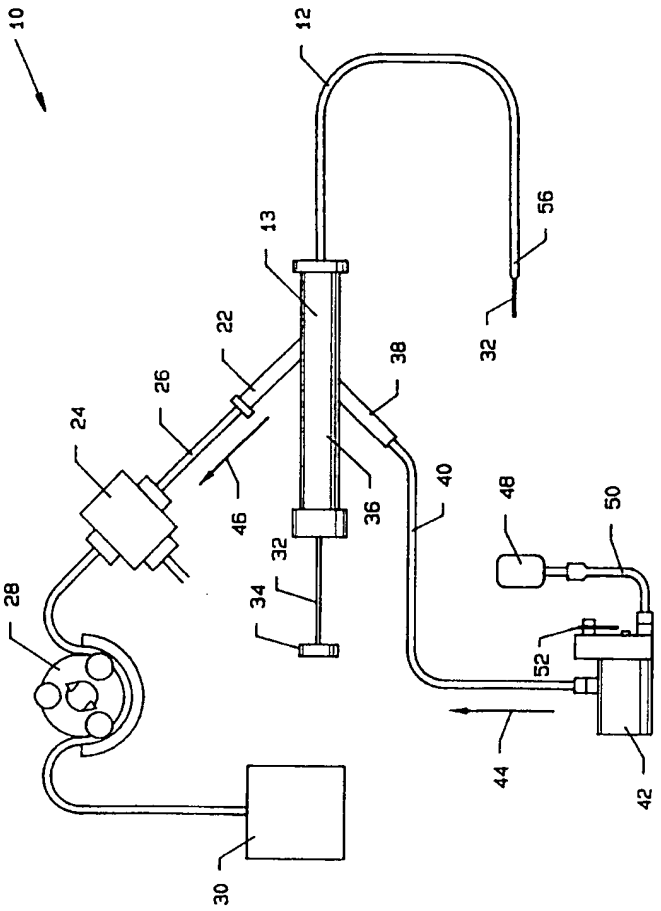

FIG. 1A

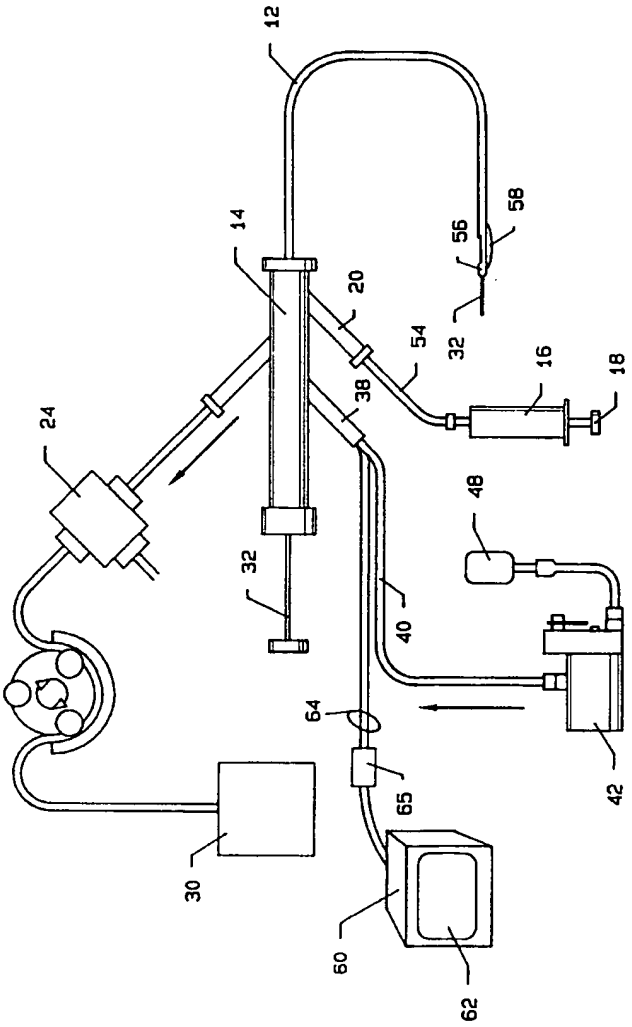

FIG. 1B

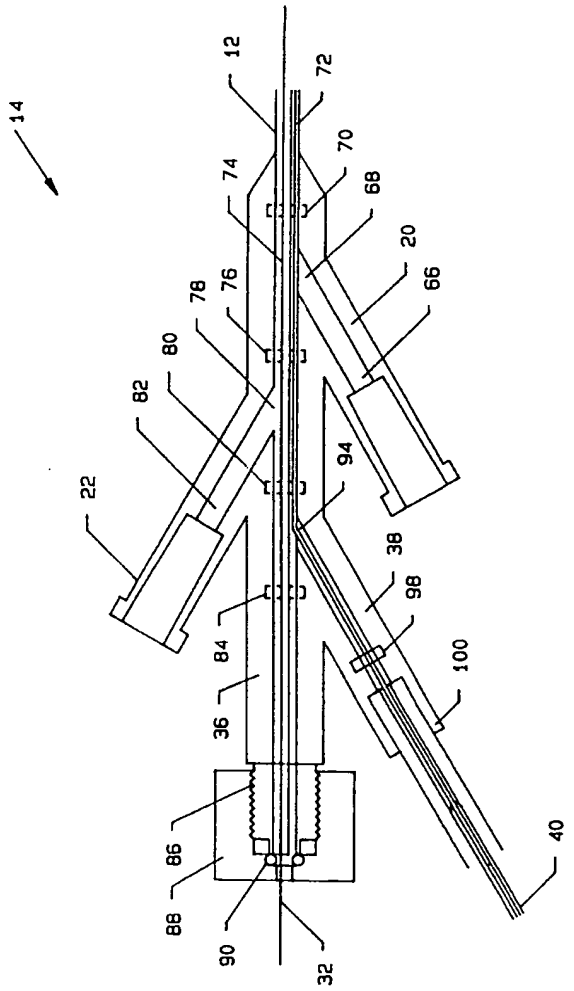

FIG. 2A

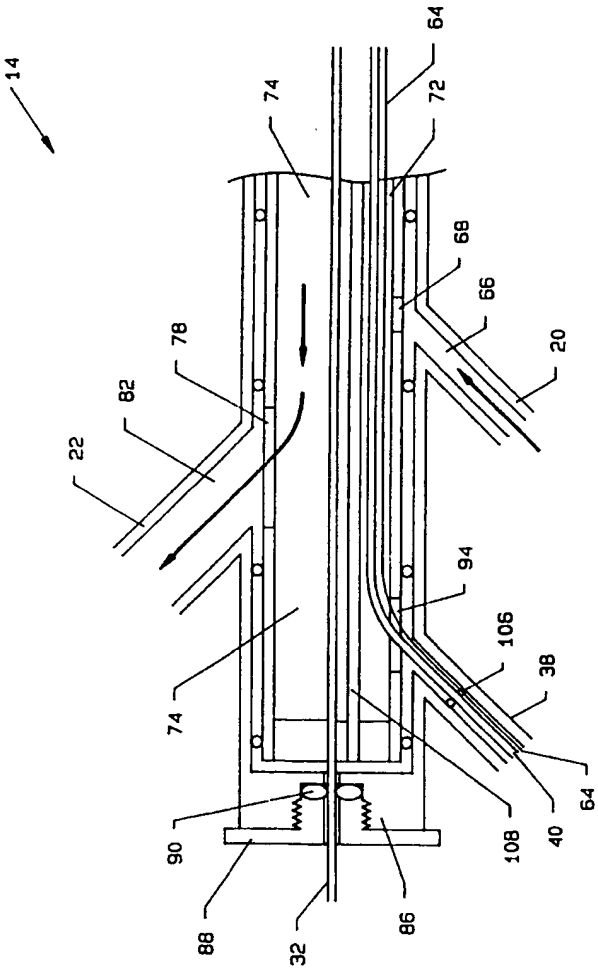

FIG. 2B

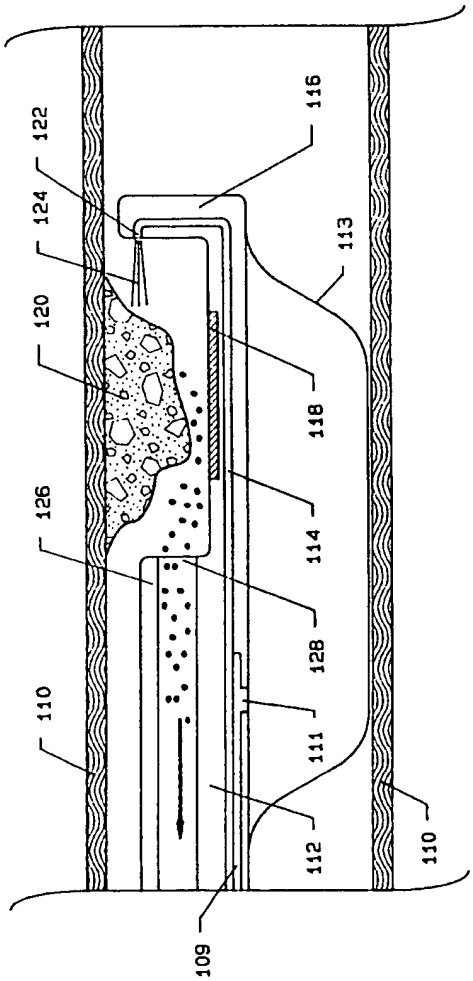

FIG. 3A

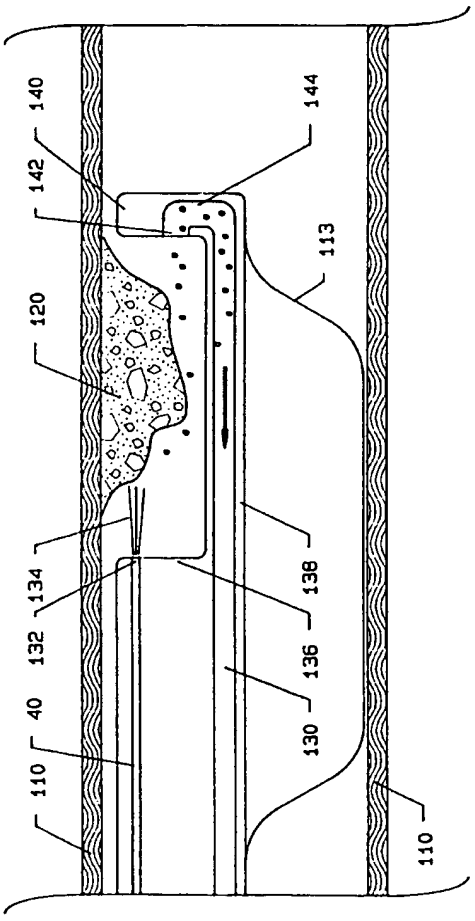

FIG. 3B

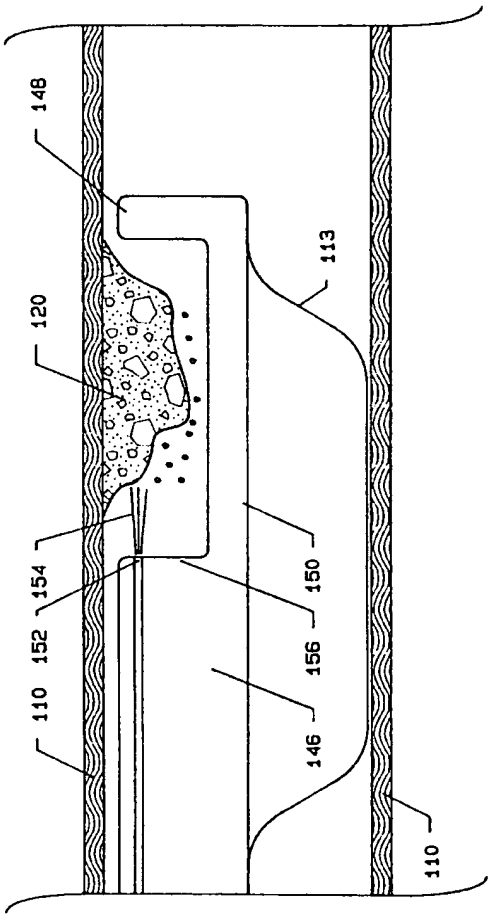

FIG. 3C

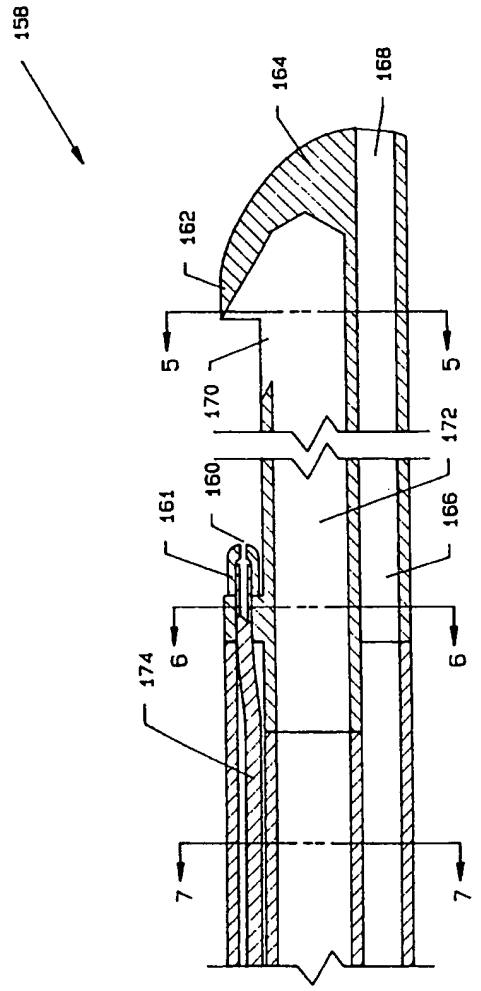

FIG. 4

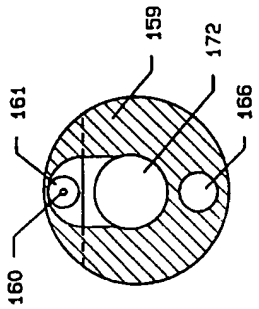

FIG. 5

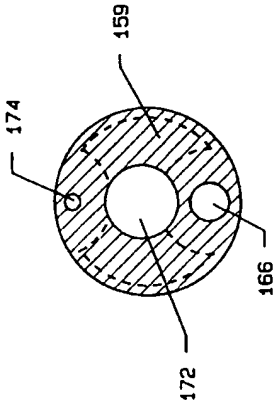

FIG. 6

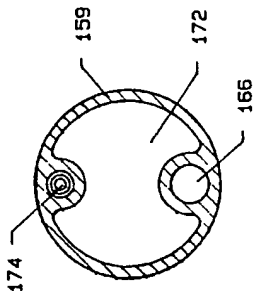

FIG. 7

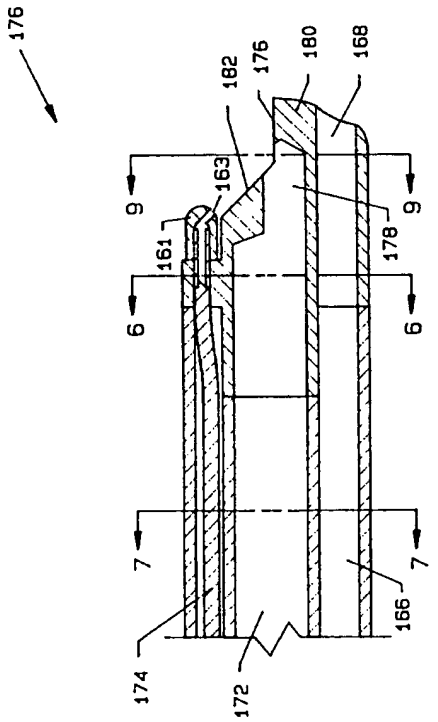

FIG. 8

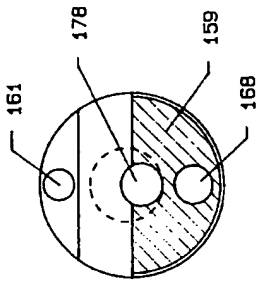

FIG. 9

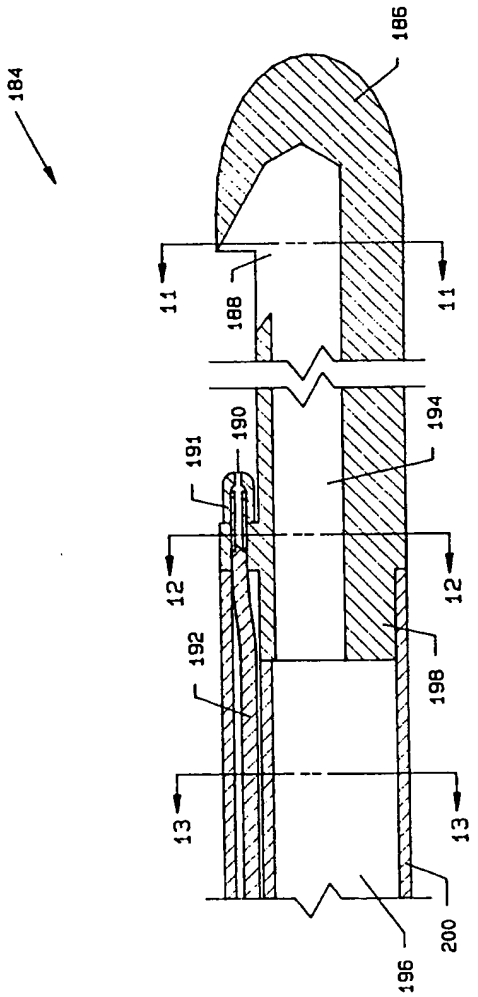

FIG. 10

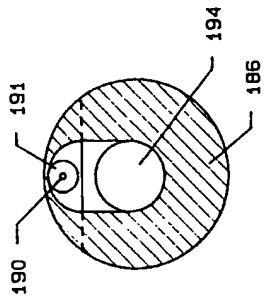

FIG. 11

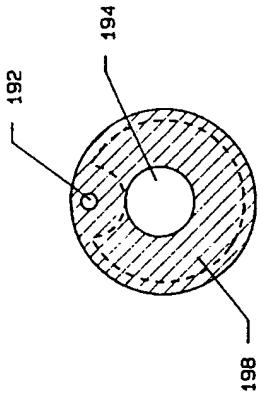

FIG. 12

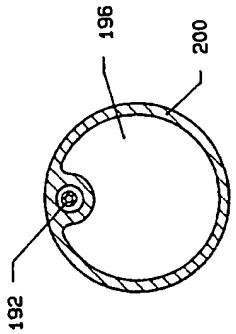

FIG. 13

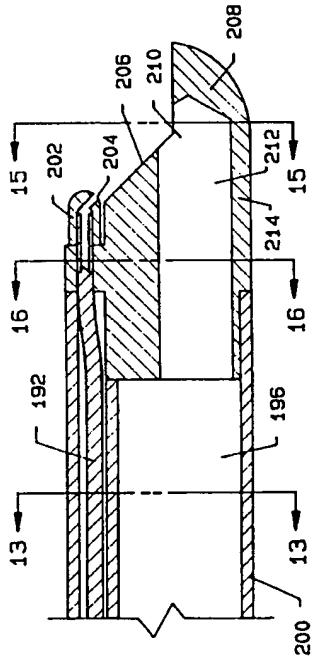

FIG. 14

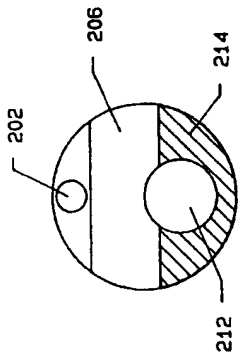

FIG. 15

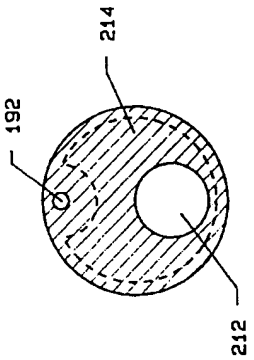

FIG. 16

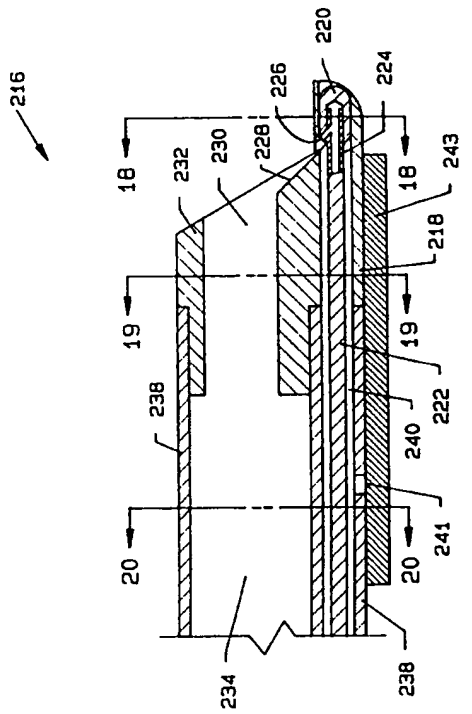
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FIG. 17

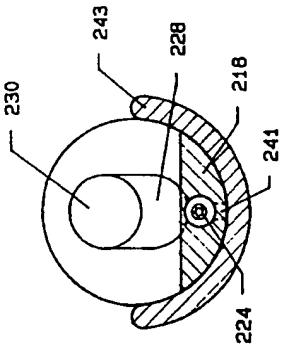

FIG. 18

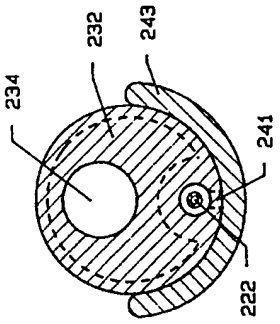

FIG. 19

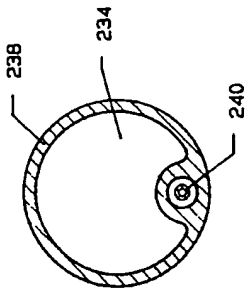

FIG.20

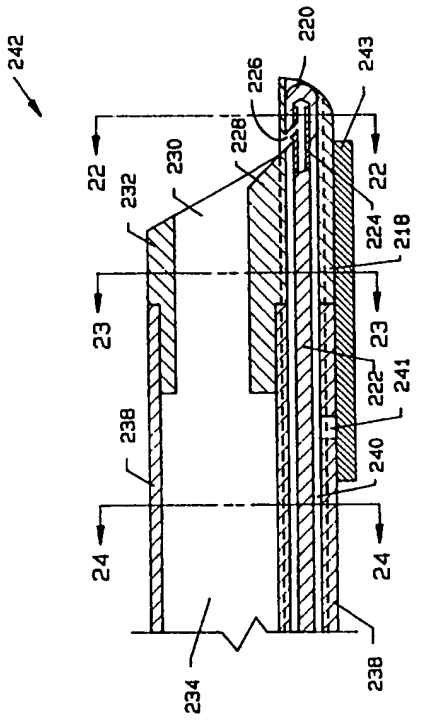
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FIG. 21

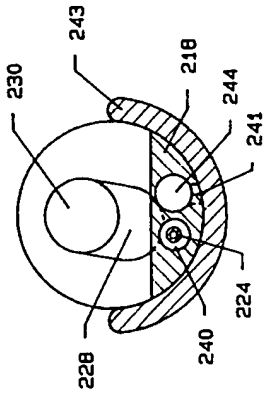

FIG. 22

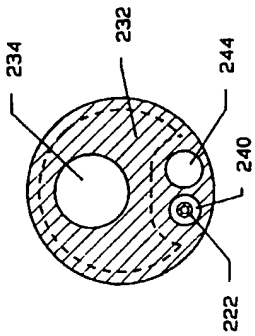

FIG. 23

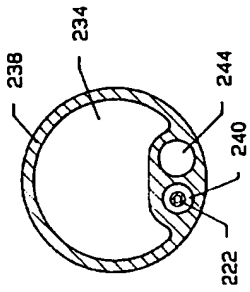

FIG. 24

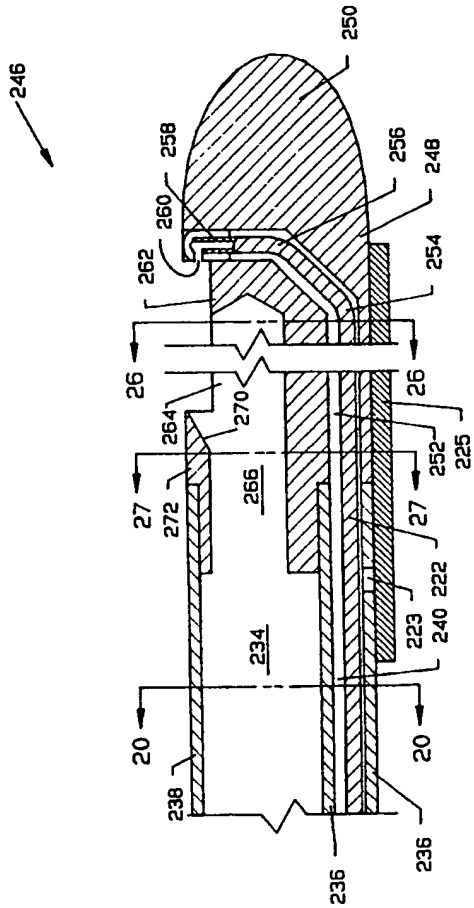
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FIG.25

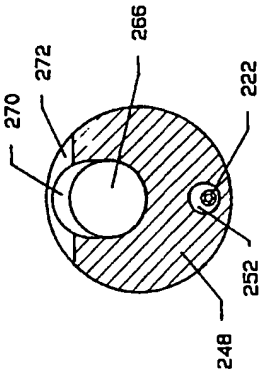

FIG. 26

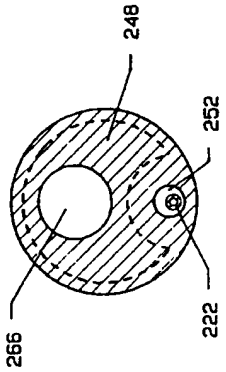

FIG. 27

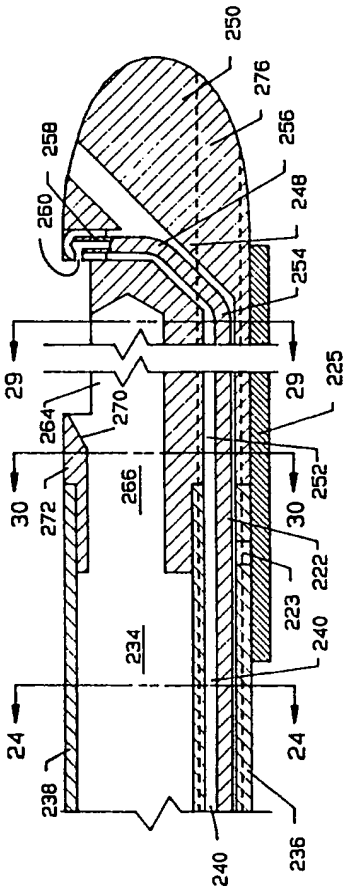
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FIG. 28

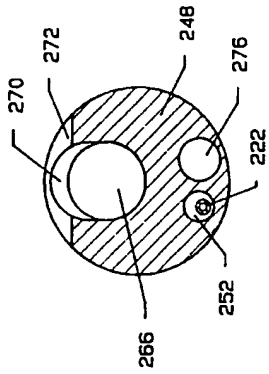

FIG. 29

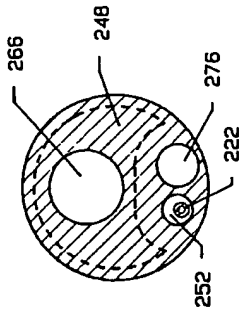

FIG. 30

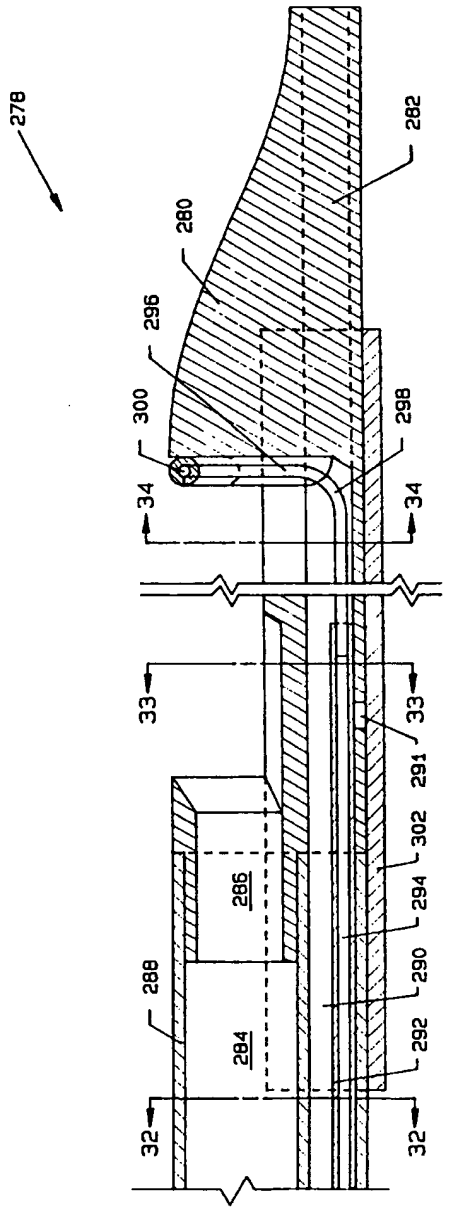
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FIG. 31

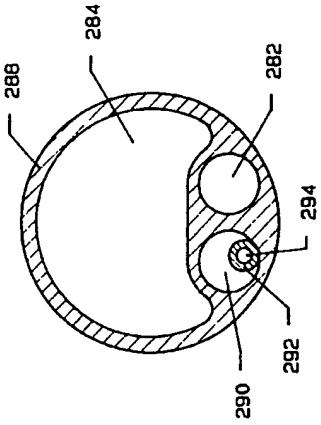

FIG. 32

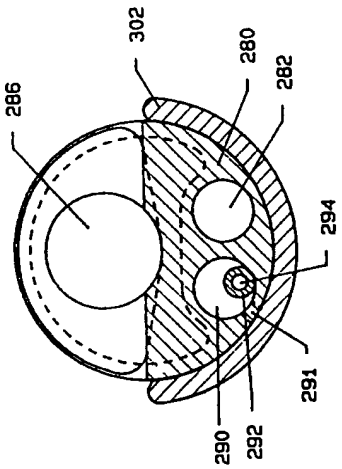

FIG. 33

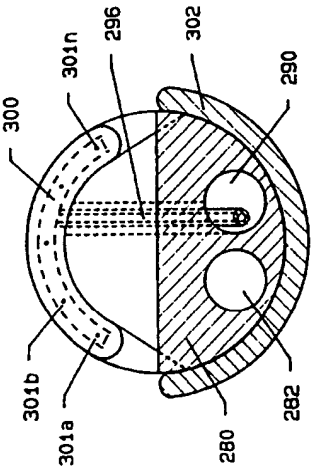

FIG. 34

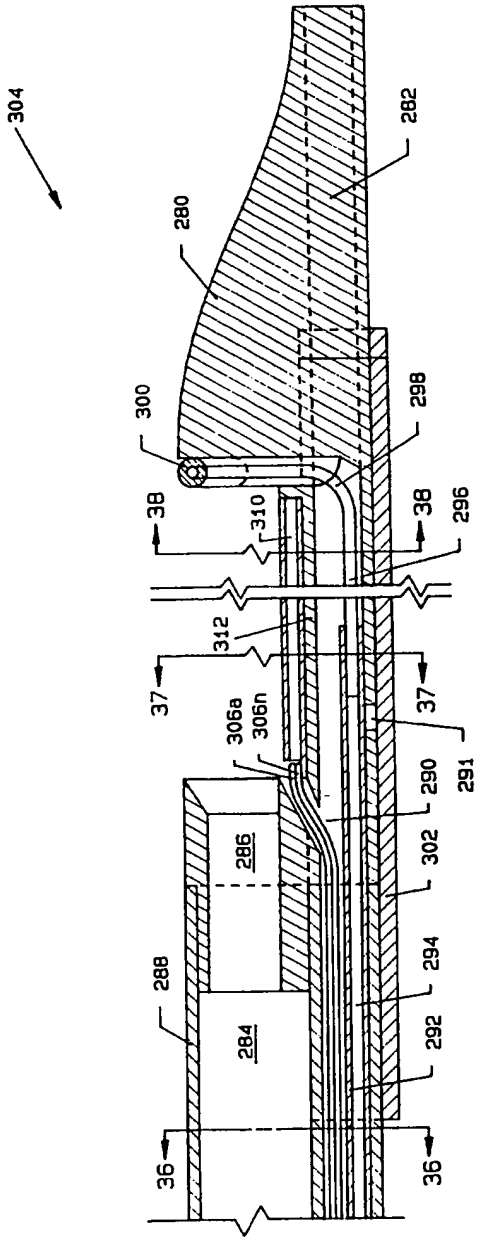
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FIG. 35

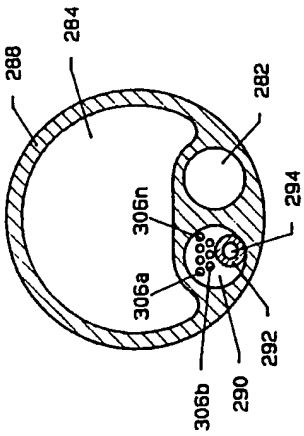

FIG. 36

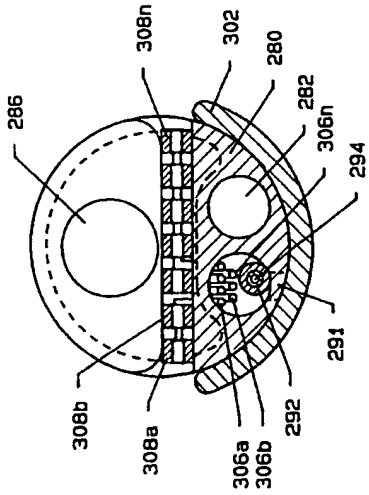

FIG. 37

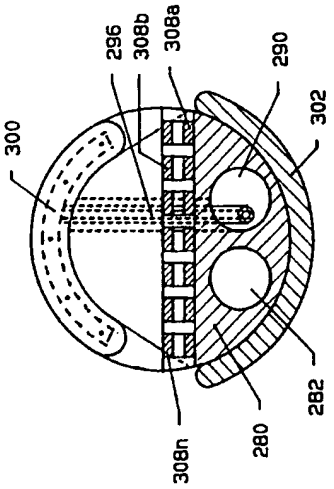

FIG. 38

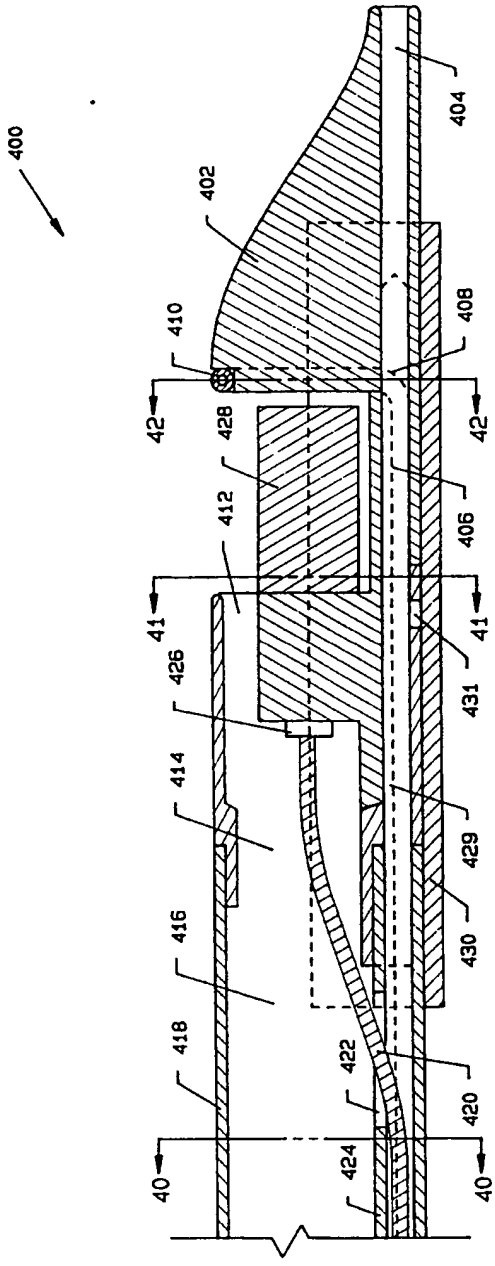
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FIG. 39

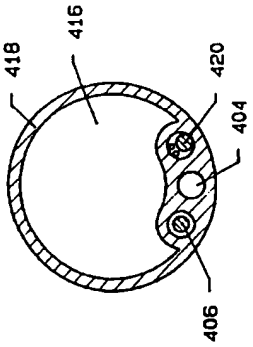

FIG. 40

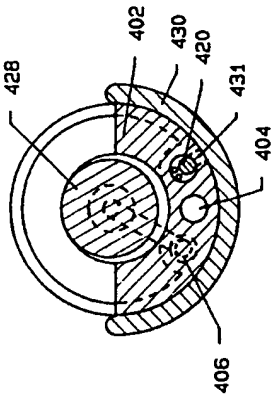

FIG. 41

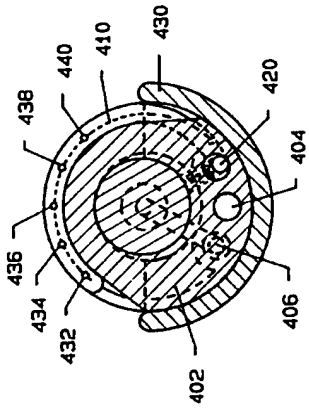

FIG. 42

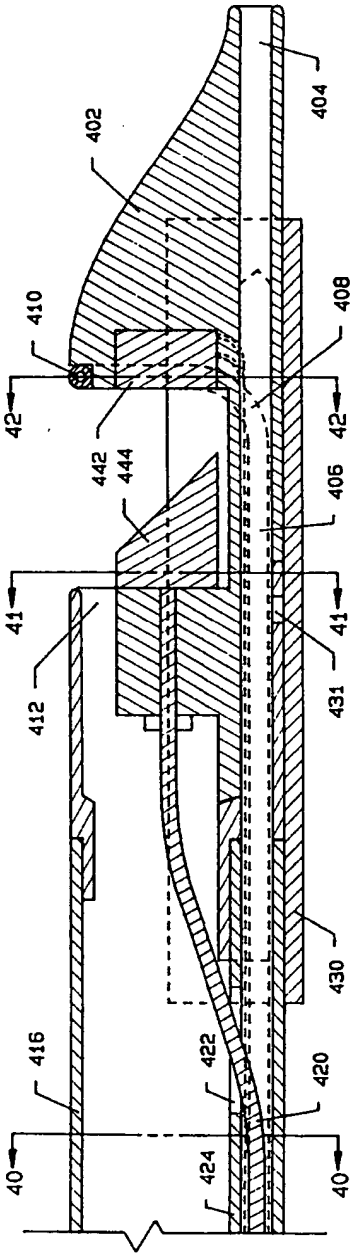
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FIG. 43

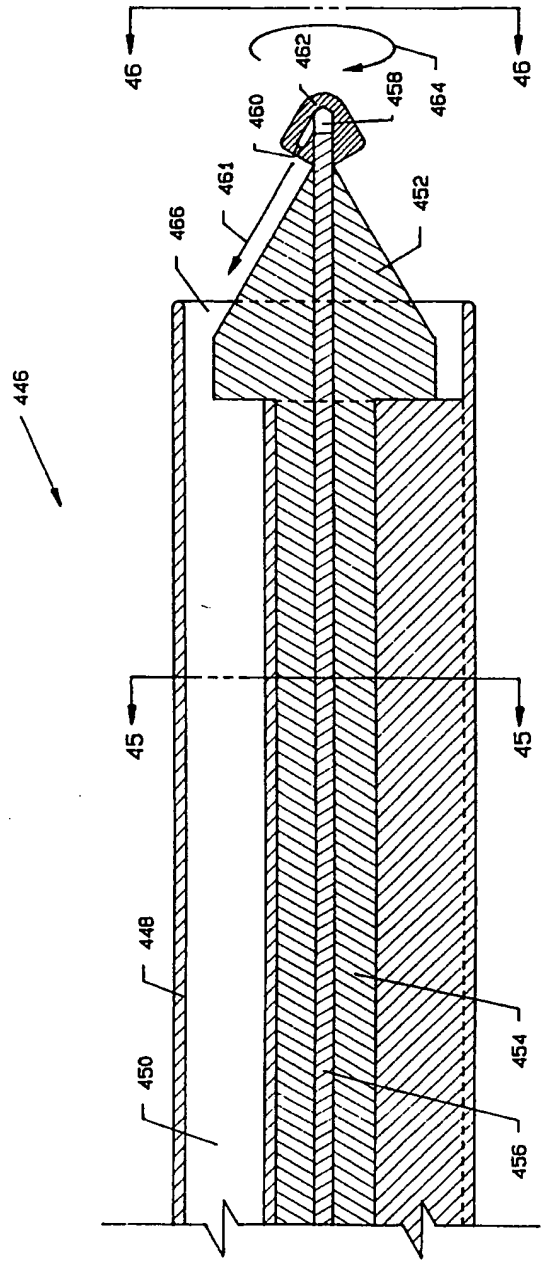

FIG. 44

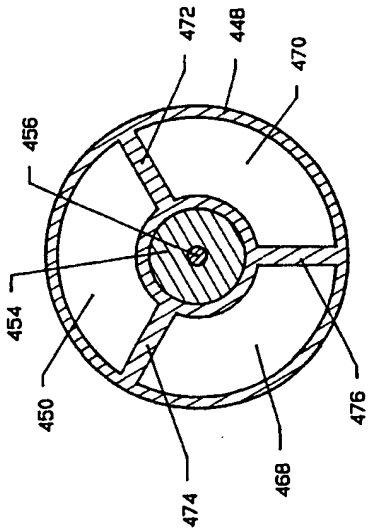

FIG. 45

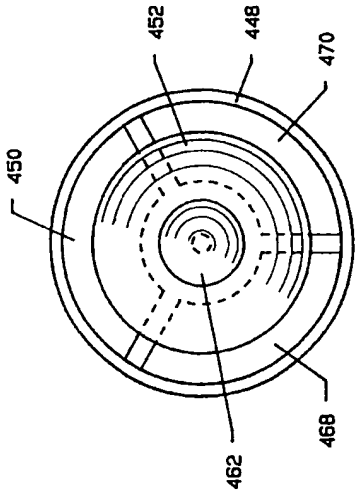

FIG. 46

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PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number: EP 91 31 0155

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	WO-A-9 005 493 (SVEDMAN) * Figures; page 4, line 30; abstract * ---	1-15	A 61 B 17/22
X	US-A-4 913 618 (ITO) * Abstract; figure 6; column 5, line 42 * ---	1-15	
X	US-A-4 950 238 (SULLIVAN) * Figure 3; abstract; column 2, lines 16-27 * ---	1	
A	EP-A-0 232 678 (NERACHER) * Abstract; column 5, line 33; figure 2 * ---	1,15	
A	DE-A-3 715 418 (OLYMPUS) * Figures 20,25 * ---	1-7,11-14	
A	JP-A-1 085 639 (OLYMPUS) * English abstract * --- -/-	8,10	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B
A 61 M

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely : 1-15

Claims searched incompletely :

Claims not searched : 16,17

Reason for the limitation of the search:

Method for treatment of the human or animal body by surgery or therapy (see art. 52(4) of the European Patent Convention).

Place of search	Date of completion of the search	Examiner
THE HAGUE	04-02-1992	BARTON S.A.

CATEGORY OF CITED DOCUMENTS

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& : member of the same patent family, corresponding document

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Application Number
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DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	WO-A-8 804 157 (LECKRONE) * Figure 23; abstract *	1-15	
A	EP-A-0 329 492 (ANGELSEN) * Abstract; figure 2 *	8-10	
A	DE-A-3 421 390 (SCHUBERT)		
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)

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